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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/556,221

04/17/2006

Yves De Koninck

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LADAS & PARRY LLP
224 SOUTH MICHIGAN AVENUE
SUITE 1600
CHICAGO, IL 60604

EXAMINER

LOCKARD, JON MCCLELLAND

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

04/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/556,221	DE KONINCK ET AL.	
	Examiner	Art Unit	
	JON M. LOCKARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30,44-53,65 and 81 is/are pending in the application.
- 4a) Of the above claim(s) 1-30,45-48,50-53,65 and 81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30,44-53,65 and 81 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 November 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/30/06, 8/27/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group V, claims 44 and 49, in the reply filed on 09 March 2009 is acknowledged. The traversal is on the ground(s) that during the international phase of the corresponding PCT application, the PCT International authorities did not raise the issue of unity of invention, and further argue that the Restriction requirement failed to establish that a search of the complete application would be an undue burden as required by MPEP 803. This is not found persuasive because the Examiner is not bound by a holding in the International application. Furthermore, it is noted this application is a national stage application and therefore U.S. restriction practice (i.e., undue search burden) does not apply. The inventions of Groups I-X do not relate to a single inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth at pg 3 of the previous Action (mailed 10 February 2009).

2. The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-30, 45-48, 50-53, 65, and 81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 09 March 2009.

Status of Application, Amendments, and/or Claims

4. The Response filed on 09 March 2009 has been entered in full. Claims 1-30, 45-48, 50-

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53, 65, and 81 have been withdrawn from further consideration as discussed *supra*. Therefore, claims 1-30, 44-49, 50-53, 65, and 81 are pending, and claims 44 and 49 are the subject of this Office Action.

Information Disclosure Statement

5. The information disclosure statements (IDS) submitted on 30 May 2006 and 27 August 2007 have been considered by the Examiner.

Drawings

6. Figures 9, 10, and 11 are objected to because 37 CFR 1.84 states that “[P]artial views intended to form one complete view, on one or several sheets, must be identified by the same number followed by a *capital* letter”. In the instant case, Figures 9, 10, and 11 have multiple panels/pages which should be labeled, for example, FIG. 9A, FIG. 9B, and FIG. 9C, and be referred to as such in the Brief Description of the Figures.

7. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should *not* be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The

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replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

8. The disclosure is objected to because of the following informalities: The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Appropriate correction is suggested.

Claim Rejections - 35 USC § 112, 2nd Paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 44 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a comparison step, i.e., the level of intracellular chloride in the presence of the test compound as compared to the level of intracellular chloride in cell in the absence of the test agent.

12. Claim 44 is rejected as being indefinite because the claim lacks a step that clearly relates

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back to the preamble. The last line of claim 1 recites wherein said decrease is an indication that said test compound may be used for treatment or prevention of pain, whereas the preamble of the claim recites a method of identifying or characterizing a compound for treatment or prevention of pain. It is thus unclear what the claimed method is intending to accomplish, and there does not appear to be sufficient methods steps to characterize the test compound.

13. Claim 44 recites the limitation "said intracellular chloride level" in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

14. Claim 49 is rejected for depending from an indefinite claim.

Claim Rejections - 35 USC § 112, 1st Paragraph (Enablement)

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 44 and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

17. Claim 44 is directed to a method for identifying or characterizing a compound for treatment or prevention of pain. However, in view of the omission of essential steps set forth under 35 U.S.C. § 112 second paragraph *supra*, the claims fail to teach how to achieve the proposed method.

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18. Claim 44 is drawn to a method for identifying or characterizing a compound for treatment or prevention of pain, said method comprising: (a) contacting a test compound with a CNS-derived cell; and (b) determining whether said intracellular chloride level is decreased in the presence of the test compound; wherein said decrease is an indication that said test compound may be used for treatment or prevention of pain. However, since the claims are missing the essential steps of: (1) a comparison step, i.e., the level of intracellular chloride in the presence of the test compound as compared to the level of intracellular chloride in cell in the absence of the test agent, and (2) sufficient methods steps to characterize the test compound, the method as claimed is not enabled.

19. Moreover, while one skilled in the art would recognize that the claimed methods could identify a test compound that decreases intracellular chloride levels in a cell, one skilled in the art would not be able to predict, with any level of certainty, whether or not the compound would actually be useful for treating pain. While the Specification establishes a nexus between the activity and expression of the chloride transporter KCC2 and pain, the claims do not require that the CNS-derived cell actually express said KCC2 transporter.

20. Furthermore, the term “prevent” is interpreted as meaning that an activity will not occur. However, it is well-known in the art that there are several factors that are involved in pain, and one skilled in the art would not predict that any compound which decreases the intracellular chloride level of a cell would prevent pain since there are multiple factors, many of which are unknown, in pain. Undue experimentation would be required of the skilled artisan to determine the quantity of the agent, the best route of administration, and the timing and duration of treatment to prevent pain.

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21. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentech, Inc. v. Novo Nordisk*, 42 USPQ 2d 100, (CAFC 1997), the court held that: “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”, and that “[t]ossing out the mere germ of an idea does not constitute enabling disclosure”. The court further stated that “when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art”, “[I]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement”.

22. Thus, in view of the omission of essential steps and the lack of guidance and the total absence of working examples, the instant specification is not found to be enabling for a method for identifying or characterizing a compound for treatment or prevention of pain. It would require undue experimentation and making a substantial inventive contribution for the skilled artisan to discover how to use the Applicants' invention as currently claimed.

Summary

23. No claim is allowed.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Manjunath N. Rao, Ph.D.**, can be reached on **(571) 272-0939**. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jon M. Lockard, Ph.D.
March 30, 2009

/Jon M Lockard/
Examiner, Art Unit 1647